JUL 2 5 2002

K021504

510(k) Summary

Submitter: Tuttnauer USA Co. Ltd.
25 Power Drive
Hauppauge, NY 11788

Phone: 800-624-5836
Fax: 516-737-0720

Contact Name: Robert R. Basile

Date Prepared: May 9, 2000

Common Name: Electronic pre-vacuum autoclave, table-top steam sterilizer

Trade Name: Tuttnauer 2540 EHS Series Table-Top Autoclave

Classification Name: Steam Sterilizer
Class II Device - 21 C.F.R. § 880.6880

Substantial Equivalence:

The Tuttnauer 2540 EHS Table-Top Autoclave is substantially equivalent to the following currently marketed device:

Company	Product Name	510(k) Clearance Number
Tuttnauer USA Co. Ltd.	2540 EHS Table-Top Autoclave	K003470

General Description:

The Tuttnauer 2540 EHS Table-top Autoclave is a steam sterilizer that provides an onboard steam generation capability. It is designed for sterilization of medical and dental instruments (wrapped and unwrapped), including complex lumened devices (such as dental handpieces), porous, hollow loads and to sterilize liquids for non-clinical applications. The sterilization medium is steam, which is directly introduced into the sterilization chamber. This eliminates the need to wait for water introduced into the chamber to boil and reach sterilization parameters.

Intended Use:

The Tuttnauer 2540 EHS Series Table-top Autoclave is intended to provide sterilization of medical and dental instruments (wrapped and unwrapped) including complex lumened devices such as dental handpieces, porous, hollow loads and to sterilize liquids for non-clinical applications. Cycle parameters are as follows:

Cycle	Ste. Temp & Range (°F)	Press. & Range (Kpa)	Time (min)	Vacuum (kPa.)	Dry Time (min)	Load Configuration
1. Unwrapped 273	273 (273-279)	305 (305 – 330)	3-1/2	20	---	Single, unwrapped instrument in center of lowest tray
2. Wrapped 273 (complex/ lumened)	273 (273-279)	305 (305 – 330)	8	25	20	4 wrapped trays arranged so that no instruments touching. Approximately 80% of area occupied.
3. Wrapped 250 (for instruments ~~or liquids~~)	250 (250-256)	205 (205 – 225)	30	25	20	Instruments 4 wrapped trays arranged so that no instruments touching. Approximately 80% of area occupied.
4. Wrapped 273 (non-lumened)	273 (273-279)	305 (305 – 330)	4	25	20	4 wrapped trays arranged so that no instruments touching. Approximately 80% of area occupied.
5. Bowie-Dick	273 (273–279)	305 (305 – 330)	3-1/2	20	2	B-D pack in otherwise empty chamber
6. Liquids	250 (250-256)	205 (205-225)	30	--	--	6 - 250 ml. Containers made of heat proof glass, each filled up to 2/3 capacity.

Dental and medical instruments were placed within self-sealing, disposable pouches. The pouches were placed upright in an instrument rack.

Technological Characteristics:

The Tuttnauer EHS Series Electronic Table-top Autoclave is a steam sterilizer that includes as its main components: a pressure vessel with steam jacket, heating elements, a dual-chamber water reservoir, a water pump and a vacuum pump. The device is identical to the predicate device, with the exception of the proposed modification to the labeling that would authorize sterilization of wrapped, non-lumened devices at 273° for four (4) minutes. The following table contains a comparison of the characteristics of the device and its predicate.

Characteristic	**2540 EHS (w/new cycle)**	**2540 EHS K003470**
Labeling/Intended Use	Auto Steam Autoclave	Auto Steam Autoclave
Process Parameters	Sterilization cycles defined by time, temp. and pressure. Wrapped, non-lumened medical instruments sterilized at 273-279°F for four (4) minutes. Complex lumened devices sterilized at 273-279°F for eight (8) minutes.	Sterilization cycles defined by time, temp. and pressure. All wrapped medical instruments, including complex lumened devices, sterilized at 273-279°F° for eight (8) minutes.
Process Monitors	Temp. and pressure gauges, digital display screen, and printer	Temp. and pressure gauges, digital display screen, and printer
Pre-Vacuum	Yes	Yes
On-Board Steam Generation	Yes	Yes
Control	Cycle time, temp., pressure, and user interface controlled by microprocessor	Cycle time, temp., pressure, and user interface controlled by microprocessor
Program Comparison	Wrapped, unwrapped, and dry	Wrapped, unwrapped, liquids, and dry
Process Equivalent Times	Sterilization times of 3-1/2, 4, 8, 30 minutes depending upon program selected	Sterilization times of 3-1/2, 8, 30 minutes depending upon program selected

Non-Clinical Testing:

Tuttnauer conducted validation studies in accordance with ANSI/AAMI ST55. Successful sterilization was accomplished in all tests performed .

Conclusion:

The Tuttnauer 2540 EHS Series Table-Top Autoclave is substantially equivalent to its predicate device, and can safely and effectively sterilize wrapped, non-lumened medical instruments at 273-279°F for four (4) minutes.

Indications for Use Statement

510(k) Number: K021504

Device Name: Tuttnauer EHS Series Table-Top Autoclave

Indications For Use: The 2540 EHS Table-Top Autoclave is intended to provide sterilization of medical and dental instruments (wrapped and unwrapped), including complex lumened devices such as dental handpieces, porous, hollow loads, and to sterilize liquids for non-clinical applications. Cycle parameters are as follows:

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Dental and medical instruments were placed within self-sealing, disposable pouches. The pouches were placed upright in an instrument rack.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use _____

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Tuttnauer USA Company Limited
C/O Mr. Todd H. Halpern
Buchanan Ingersoll, P. C.
1776 K Street N.W., Suite 800
Washington, D.C. 20006-2365

Re: K021504
Trade/Device Name: Tuttnauer 2540 EHS Series Table-Top Autoclave
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May 9, 2002
Received: May 9, 2002

Dear Mr. Halpern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K021504

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(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Daniel for Clin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021504